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10/585,839	06/09/2008	Peter Andrew Priest	1653/97808	7874
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Husch Blackwell LLP			CHAPMAN, GINGER T	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/585,839

Applicant(s)

PRIEST ET AL.

Examiner

GINGER T. CHAPMAN

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-27, 31-34 and 36-39 is/are pending in the application.
- 4a) Of the above claim(s) 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-27, 31-34 and 36-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 February 2011 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No.(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

The examiner notes that the present numbering of previously presented claims 37, 38 and 39 appears to be a typographical error because the claims are misnumbered such that there are two claims numbered 35 and two claims numbered 36. This appears to be a typographical error as previously presented claims 37, 38 and 39 are misnumbered as claims 35-37.

Misnumbered claims 35-37 have been renumbered 37-39.

Claim 20 is objected to because of the following informalities: lines 6-7 recite “for pressing the proximal end of the connector into contact with the exterior surface of the subject whereby to connect it to the fistula.” The use of the pronoun “it”, used to refer to a thing previously mentioned or easily identified, may cause confusion over whether the “it” being referred to is the claimed “exterior surface of the subject” or the claimed connector because “it” is immediately preceded by “the subject” rather than the connector, thus appearing to refer to the subject being connected to the fistula rather than the connector connected to the fistula. Appropriate correction is required.

Status of the Claims

Claims 20 and 33 are amended, claims 28-30 and 35 are canceled, claims 20-27, 31-34 and 36-39 are pending in the application, claim 30 is withdrawn from consideration as being drawn to a nonelected invention, claims 20-27, 31-34 and 36-38 are examined on the merits.

Drawings

The drawings were received on 28 February 2011. These drawings are acceptable.

Withdrawn objections:

The objection to the drawings for failing to show every feature of the invention specified in the claims is withdrawn in view of Applicants' amendment.

Response to Arguments

Applicant's arguments with respect to claims 20-27 and 31-34 and 36-38 have been considered but are moot in view of the new ground(s) of rejection. Applicants' arguments are drawn to the claims as amended and are answered in the detailed analysis of the claims below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 20-26, 31-34, 36 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen (EP 0 098 718 A1) in view of Kay (US 4,592,750).

With respect to claim 20, as best depicted in Figures 1 and 4-6, Jensen discloses an apparatus for connecting a drainage bag 10 to a fistula of a subject (page 16, lines 3-11), including a connector 28 (Figures 3-6; page 17, lines 16-20) in the form of an elongate flexible

tubular member 36 (page 20, lines 15-20; Figures 1, 3 and 6) having an inlet aperture 34 (page 17, lines 22-24; Figures 1 and 3) at a proximal end 29 (page 17, lines 14-15) for receiving waste material from the fistula and an outlet aperture 38 (page 18, lines 7-9) at a distal end 31 for engagement 18 with the drainage bag 10 through which waste material travels before entering the drainage bag (page 17, lines 22-24; Figure 3-6), and means 22 for applying a force to the connector for pressing the proximal end of the connector into contact with the exterior surface of the subject whereby to connect it to the fistula (page 16, lines 20-23).

Jensen discloses the claimed invention except for expressly disclosing means for applying a force to the distal end of the connector. As best depicted in Figures 1 and 2 and page 17, lines 19-23, Jensen discloses means 22 for applying a force to the connector 28 for pressing the proximal end 29 of the connector into contact with the exterior surface of the subject whereby to connect it to the fistula, thus providing motivation for pressing the proximal end 29 of the connector into contact with the exterior surface of the subject, i.e. the wearer.

Jensen discloses the means 22 for applying force is located on annular member 20 which is located on the body-facing side of the pouch 10 and couples pouch 10 to the connector 28 at the distal end 31 of the connector. The means 22 for applying force is located in the same location as the instant means for applying force, i.e. Jensen's elements 20 and 22 are located at the distal end of the connector and act to secure the connector to the subject / wearer in the substantially identical manner as the instant means. Jensen's means for applying force comprise belt-receiving elements 22 located on annular member 20 that connect member 20 and pouch 10 to a belt designed to extend around the body of the subject / wearer in the abdominal region. The instant means for applying force comprises a belt or abdominal strap that extends around the

subject /wearer. Thus the means for applying force disclosed by Jensen is located in the substantially same location at the distal end 31 of the connector 28 and performs the substantially identical function in the substantially identical manner, thus the examiner has a reasonable basis to contend that the means for applying force, i.e. the belt-receiving elements 22 and the belt of Jensen applies a force to the distal end 31 of the connector 28 for pressing the connector 28 into contact with the exterior surface of the subject to connect it to the fistula.

The examiner notes that the instant Specification, in particular at PG-Publication paragraphs [0018 and 0039-0043] contains no disclosure of how the instant means for applying force, disclosed as a belt, is received onto the instant connector or onto the instant ostomy bag.

Kay, at column 6, lines 1-10, provides motivation to solve the problem of adhesive means irritating the skin of a wearer and belts that can become dislodged or improperly worn by providing a belt that applies pressure, i.e. a force across the distal end of a faceplate / connector for pressing the proximal end of the connector into contact with the exterior surface of a subject / wearer whereby to connect it to the fistula. As best depicted in Figure 10 Kay teaches a means 60 for applying force to the distal end of connector 22 for pressing the proximal end of the connector 22 into contact with the exterior surface of the subject / wearer whereby to connect the connector 22 to the fistula (column 6, lines 15-20). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the means for applying force of Jensen applying force to the distal end of the connector as expressly taught by Kay since Kay states, at column 6, lines 19-20, lines 37-38 and lines 41-44, that the benefit of such is that it applies an even pressure across the faceplate toward the user producing a maximal

faceplate to body seal thereby providing improved stoma protection and security and allows easy daily removal of the faceplate for hygiene of the appliance and stoma.

With respect to claim 21, Jensen discloses wherein the means 22 for applying a force to the distal end of the connector is a belt or abdominal strap (page 16, lines 20-23).

With respect to claim 22, as best depicted in Figure 6, Jensen discloses wherein the flexible tubular member 36 is resiliently deformable in a longitudinal direction (page 20, lines 14-25).

With respect to claim 23, as best depicted in Figures 3-6, Jensen discloses wherein at least a portion 46 of the flexible tubular member 36 is ribbed (page 21, lines 16-23).

With respect to claim 24, Jensen discloses wherein the apparatus further includes an inlet flange 26 (Figures 1 and 2); 86 (Figure 6) around the inlet aperture 34 (page 17, lines 10-24).

With respect to claim 25, Jensen discloses wherein the inlet flange 26, 86 (Figures 1, 2 and 6) is resiliently deformable 28, 88 (page 17, lines 10-11; page 18, lines 16-17; page 20, lines 1-4).

With respect to claim 26, as best depicted in Figures 2 and 6, Jensen discloses wherein the apparatus further includes an outlet flange 33 around the outlet aperture 38 (page 18, lines 7-15).

With respect to claim 31, Jensen discloses wherein the flexible tubular 36 member is variable in length (page 20, lines 15-19; page 21, lines 16-18; page 23, lines 16-20).

With respect to claim 32, Jensen discloses the claimed invention except for expressly disclosing wherein the length of the flexible tubular member may be varied by up to 4 cm in

length. Jensen discloses varying the length of the tubular member as the member extends, thus providing motivation for such (page 24, lines 13-20).

At page 4, lines 12-18 Jensen discloses the fistula area and skin surrounding a stoma/fistula is sensitive and painful; at page 7, line 26- page 8, line 5, that a disadvantage is when the pouch inner wall surface contacts the stoma and thus the pouch surface should be maintained at a position spaced from the stoma; at page 9, lines 20-30, the connector is of sufficient strength to maintain the pouch at a sufficient distance from the stoma and the connector extends such a distance; at page 12, lines 9-15, discloses that the connector, when extended, the flexible tubular member maintains the pouch at a location spaced from the fistula/stoma; At page 13, lines 16-21, the connector should have strength sufficient aid in supporting the pouch as the pouch becomes heavier due to accumulation of waste therein; at page 23, line 26 to page 24, line 9, discloses that the only limitation on the length of the connector is that it must have sufficient strength to withstand the weight of the pouch.

Thus Jensen provides motivation to vary the length of the flexible tubular member balanced between a length sufficient to keep the pouch away from the stoma and a length whereby the weight of the filling pouch is supported by the member, thus disclosing the general conditions of the claim of varying the length of the flexible tubular member. Any particular length will also vary depending on the condition of a wearer's fistula and degree of sensitivity or pain. Therefore, in view of the teachings of Jensen, it would have been obvious to one of ordinary skill in the art at the time the invention was made to vary the length of the flexible tubular member as taught by Jensen by up to 4 cm in length as claimed in order to provide a connector that protects the fistula while still supports the weight of the pouch, and since it has

been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

With respect to claim 33, Jensen discloses the claimed invention except for a retention member to prevent movement of an intestine of the subject through the connector into the drainage bag. Jensen, at page 7, lines 26-28, provides motivation to prevent the stoma, i.e. fistula from unnecessary contact with the pouch of the apparatus. Kay, at column 3, lines 4-6, provides motivation to protect the stoma / fistula from pain and injury resulting from contact with surfaces during daily activity, thus providing motivation for such. As best depicted in Figures 1 and 5-10, Kay teaches a connector 22 comprising retention member 38 which prevents fistula/stoma contact and also would perform the function of preventing movement of an intestine of the subject through the connector while still permitting outflow of stomal waste through the connector (column 5, lines 14-30). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the retention member of Kay for the connector of Jensen since Kay states, at column 5, lines 24-29, that the benefit of providing such a member is that it prevents the stoma from contact, i.e. the stoma cannot protrude past the member, while still permitting stomal outflow, thereby providing a more sanitary and comfortable appliance.

With respect to claim 34, Jensen discloses wherein the connector (Figures 1 and 3) is formed, at least in part, of a flexible plastics or rubber or foam material (page 18, lines 16-17; page 20, lines 1-4, lines 19-20 and lines 24-26).

With respect to claim 36, Jensen discloses wherein the connector is formed, at least in part, of a hypo-allergenic material (page 2, line 27 to page 3, line 1).

With respect to (renumbered) claim 38, as best depicted in Figure 1, Jensen discloses drainage appliance 33 comprising apparatus according to claim 20 interconnected with a drainage bag 10.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen (EP 0 098 718 A1) in view of Kay and further in view of Olsen (US 5,501,678).

With respect to claim 27, Jensen discloses the claimed invention except for the outlet flange is provided with an adhesive layer on at least a portion thereof for adhesive engagement with a drainage bag. Jensen discloses the outlet flange 33 is provided with formations for complementary inter-engagement with corresponding formations on a drainage bag, thereby providing motivation to engage the outlet flange with the drainage bag. Olsen, at column 1, lines 5-10 and lines 37-40, teaches a connector that can be adhered to the skin of a user, a collection bag or a coupling part therefor being adhered to the appliance side of the connector and thus provides motivation for adhesive engagement with a flange and drainage bag. Olsen, at column 4, lines 10-14, teaches the equivalency of using either adhesive or interengaging coupling parts to provide engagement between fistula / stoma connectors and drainage bags. As best depicted in Figure 2, Olsen teaches an outlet flange 10 provided with an adhesive layer 21 on at least a portion thereof for adhesive engagement with a drainage bag (column 2, lines 42-47; column 4, lines 1-20). Therefore it would have been obvious to one having ordinary skill in the art to provide the engagement between the connector and drainage bag with adhesive of Olsen for the engagement of Jensen since Olsen teaches their equivalency and both methods perform the

substantially identical function of providing engagement and it has been held that substitution of equivalent methods requires no express motivation, as long as the prior art recognizes equivalency. *In re Siebentritt*, 152 USPQ 618 (CCPA 1967).

Renumbered claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen in view of Kay and further in view of von Dyck (US 6,033,390).

With respect to (renumbered) claim 37, Jensen discloses the claimed invention except for the connector is formed, at least in part, of foam. Jensen discloses, at page 17, lines 6-13, providing the connector with a porous material in contact with the wearer's skin around the stoma, thus providing motivation for a porous type of material which can be foam as foam is known to be porous material, but does not expressly disclose any particular foam. As best depicted in Figures 4 and 11, von Dyck teaches a connector (Figure 11) formed at least in part, of foam 58 (Figure 4; column 9, lines 1-15). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the connector of Jensen with a foam part as taught by von Dyck since von Dyck states, at column 9, lines 1-7, that the benefit of such is that the foam protects the sensitive skin of the stoma and additionally provides some cushioning between the skin and the appliance, thereby providing a more comfortable, less painful appliance.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINGER T. CHAPMAN whose telephone number is (571)272-4934. The examiner can normally be reached on Monday through Friday 9:30 a.m. to 6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Ginger T Chapman/
Examiner, Art Unit 3761
05/06/11

/Melanie J Hand/
Primary Examiner, Art Unit 3761